

**K232625 Steriking® Pouch for Robotic Instruments**Jun 7, 2024  
283 days to decisionK232625 · Product code: **FRG** · General Hospital  
Source: <https://www.510kdatabase.net/k232625/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wrap, Sterilization (FRG)
Date received	Aug 29, 2023
Decision date	Jun 7, 2024
Days to decision	283 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Wipak OY</b>
Location	Nastola, FI
Contact	Hanna Marttila
510(k) history	7 submissions · 7 cleared · 2022-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Compliance Systems International, LLC</b>
Contact	Amanda Singleton

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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